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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,646

01/29/2004

Roger P. Jackson

10,390

5706

7590
John C. McMahon
PO Box 30069
Kansas City, MO 64112

08/27/2009

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

08/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,646	Applicant(s) JACKSON, ROGER P.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This finality of the Office action of July 14, 2008 is hereby withdrawn.

In view of the appeal brief of April 2, 2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Dent (GB2140523). Dent discloses, at least in figures 9 and 14-16, a plug closure including a closure (14A) having at least a pair of bores (20) each positioned in spaced relationship to both an axis of the closure and to a periphery of the closure, the bores being in parallel to the axis and being accessible from a top of the closure; and a break-off head (14B—threaded portion) attached to the top of the closure and breakable therefrom upon application of a preselected torque to the break-off head, the break-off head being free of bores providing axial access the bores by a removal tool, and the bores being positioned so as to be inaccessible by a removal tool until the break-off head is broken from the closure. Note: The device as shown in fig. 14 has been turned upside-down, so that the closure is element 14A and the head is element 14B. Note also: The introductory statements of intended use (e.g., “for use with an open-headed medical implant having a pair of spaced and interiorly threaded arms”) have been carefully considered but deemed not to impose any structural limitations on the

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claims patentably distinguishable over Dent's device, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-3, 5, 6, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (5,797,911) in view of Dent (GB2140523), and further in view of Johnson (1,300,275). Sherman et al. disclose, at least in figures 1 and 2; the invention substantially as claimed. Sherman et al disclose a closure plug (14) usable in an open-headed medical implant having a pair of spaced and interiorly threaded arms, where the plug includes a body (55) with a radially outward surface with a thread thereon; top and bottom surfaces, where the plug

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includes a break-off head (56) attached to the body and being breakable from the body at a preselected torque; the break-off head being positioned so as to be axially located above the body and being free of pass-through openings that would allow access to at least one bore positioned between a central axis of the bone and a periphery of the body; where the body is generally cylindrical in shape, where the body includes a neck (58), and where the break-off head has a tool-grippable outer surface. However, Sherman et al. do not disclose that the body has at least one bore or a pair of bores sized and shaped to receive a tool and extending generally axially entirely through the body from top to bottom thereof, where each bore is spaced from a central axis of the body and a periphery of the body, and where the plug includes a tool having a grippable handle and an engagement face including a post extending parallel to an axis of rotation of the tool for each body bore.

Dent teaches, in figures 14-16, a similar device having a closure plug with a generally cylindrical body (14B, 12) having a (threaded) radially outward surface that has a mating guide and advancement structure (at 12), a top surface (18) and a bottom surface (between 14B and 12), a pair of bores (20) spaced from and positioned between both a central axis of the body and a periphery of the body, a break-off head (14A) joined to the body by a neck positioned between the bore, and where the plug includes a tool having a grippable handle and an engagement face including a post extending parallel to an axis of rotation of the tool for each body bore (See also page 2, lines 112-118 for a "tool with a frusto-conical cavity" and "drive pins"). It would have been obvious to one having

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ordinary skill in the art at the time the invention was made, in view of Dent, to modify the body of the device of Sherman et al., so that it includes at least one bore or a pair of bores in the top surface of the body, where each bore is sized and shaped to receive a removal tool, where each bore is spaced from and positioned between a central axis of the body and a periphery of the body, and where the plug includes a tool as claimed. Such bores would allow convenient removal of the plug or body from a patient's body should a surgeon decide that the plug or body needs to be removed or repositioned, while the tool with a posts would allow removal of the plug or body, when it is installed in an implant, where other conventional wrenching tools would not have access.

However, Sherman et al. or Sherman et al. in combination with Dent do not disclose that each bore extends axially from the bottom surface to the top surface. Johnson teaches, at least in figures 1 and 4 and in lines 70-102; a plug including a body with a bore positioned between a central axis of the body and a periphery of the body, where the bore extends through the entire length of the body (i.e. the bore is extendable from the bottom surface to the top surface). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Johnson, to form and position the bores of the body of the plug of Sherman et al. in view of Dent (without pass through openings in the break-off head), such that the aperture is positioned between a central axis of the body and a periphery of the body and extends through the entire length of the body. Such an aperture would allow a pin of a removal tool to securely hold the plug during turning and removal of the plug.

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6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (5,797,911) in view of Dent (GB2140523) and Johnson (1,300,275), and further in view of Wagner (5,334,203). Sherman et al. in view of Dent and Johnson discloses the invention substantially as claimed, but do not disclose three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Wagner teaches, at least in figure 1, a closure plug (38) including three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wagner, to modify the device of Sherman et al. in view of Dent and Johnson, so that there are three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Such a configuration of bores (and a tool as taught by Wagner) would allow the tool to grip a closure plug and exert more torque for turning the plug and ease its installation or removal.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (5,797,911) in view of Dent (GB2140523) and Johnson (1,300,275), and further in view of Parker et al. (6,053,078). Sherman et al. in view of Dent and Johnson discloses the invention substantially as claimed, but do not disclose four spaced tool receiving bores as claimed. Parker et al. teach, at least in figure 2A and in col. 3, lines 36-46 and col. 4, lines 9-11; a plug (10) with at least four spaced tool receiving tool receiving bores as claimed, which are configured to receive a tool (20). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Parker et

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al., to modify the device of Sherman et al. in view of Dent and Johnson, so that there are four spaced tool receiving bores as claimed. Such a configuration of bores would allow the tool to grip the closure plug and transfer more torque for turning the plug and ease its installation or removal.

8. Claims 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (5,797,911) in view of Dent (GB2140523) and Johnson (1,300,275), and further in view of Reed (6,261,039). Sherman et al. in view of Dent and Johnson discloses the invention substantially as claimed, but do not disclose that the body includes an axial extending bore from the bottom to near the top thereof or a threaded axial extending bore passing entirely through the body from a top to a bottom thereof, where the axial bore is located beneath the neck and is accessible from a top of the body when the break-off head breaks away from the body. Reed teaches, in figures 1-3, 11-13, 15, and 16, a closure plug body (10) including a threaded axial extending bore (114) from the bottom to near the top thereof, where the axial bore is located beneath (and through) a neck (30) and is accessible from a top of the body when a break-off head (20) breaks away from the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Reed, to include a threaded axial extending bore as claimed in the closure plug of Sherman et al. in view of Dent and Johnson. Such a modification would allow the device of Sherman et al. in view of Dent and Johnson to be used in thread repair, where the axial bore is adapted to receive a desired threaded fastener.

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Sherman et al. in view of Dent and Johnson also do not disclose a threaded set screw sized and shaped to be received in the axial bore, where the set screw is sized and shaped to extend outward from the body bottom surface when the screw is fully installed therein. Reed also teaches a set screw (300) to be received in the axial bore. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to include a set screw in the device of Sherman et al. in view of Dent and Johnson, as modified by Reed. Such a screw would allow the thread of the axial bore to remain clean and retain its integrity during application of torque to the break-off head. Moreover, it would have been obvious to one having ordinary skill in the art to size the screw, so that it extends outward from the body bottom surface when the screw is fully installed therein, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773